

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	David F. Davenport, <i>et al.</i>
Application No. 10/692,063	Filing Date: October 23, 2003
Title of Application:	Method And Composition For Feeding Mammals
Confirmation No. 7269	Art Unit: 1616
Examiner	

Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT UNDER 37 C.F.R. §1.132

I, Dr. David F. Davenport, hereby declare and state as follows:

1. I am the CEO of MD's Choice, Inc. the assignee of U.S. Patent Application No. 10/693063 entitled "Method and Composition for Feeding Mammals" (the "063 Application") and a named inventor to the '063 Application.
2. I have been CEO of MD's Choice, Inc. since November 1998.
3. In late summer of 2001 MD's Choice began development of an enteral nutrition program to treat a horse in critical care condition.
4. In order to test whether the enteral nutrition program was effective to treat a horse in critical condition, it was necessary for MD's Choice to provide the enteral nutrition program to veterinarians and veterinary hospitals treating critically ailing

horses because the proposed components, such as whey powder – even with added lactase, in a horse feed may lead to life threatening adverse effects.

5. The first test began on or about August 23, 2001, when MD's Choice provided Lytle Creek Farms Inc. with a 4 part enteral nutrition program to treat an 800 kg gelding. Lytle Creek Farms was provided with amounts of the 4 part program believed to be sufficient to treat the gelding.

6. This testing was recorded on MD's Choice's invoice shown in Exhibit A. The invoice recorded the recipient of the program, in this case Lytle Creek Farms, the amount provided and instructions accompanying the program. Exhibit A shows that Lytle Creek Farms was instructed to add water to the liquid meal for incubation, discard unused portion after 48 hours, and refrigerate liquid vitamin. The feeding amounts and frequencies for adult horses and foals were also provided.

7. After providing the enteral nutrition program as instructed, Lytle Creek Farms reported the results of the treatment to MD's Choice. The results of this treatment are discussed in paragraph [0116] of the Application.

8. The composition provided to Lytle Creek Farm is a combination of glutamine, pre- and probiotics, N-acetyl-glucosamine, arginine and carnitine in an effective

proportion as shown in the table of Functional Food Component in paragraph [0112] of the Application, and a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% and less than 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase.

9. In the above composition, whey powder and lactase are in an effective and optimal proportion wherein the amount of lactase is determined based on a calculation method described in paragraphs [0052] to [0059] of the Application.

10. The ability to test the enteral nutrition program depended on the availability of a critically ailing horse. Because of limited availability of critically ailing horses resulting from the same disease with same symptom, a direct comparison study was not performed.

11. However, the results from Lytle Creek Farms are unexpected because positive responses were observed within a short period of time after feeding the horses in critical conditions with the compositions, comparing to the common knowledge about the normal recovery period necessary for the horses with similar conditions.

12. For example, in one horse with diarrhea secondary to heavy parasitism, a positive response was seen within 12 hours of administration, as recorded in paragraph [0116] of the Application. In contrast, it is well known that it usually takes about one week for a horse with a simple diarrhea to show signs of recovery even with the known feeding composition for sick horses at the time of the invention.

13. Another unexpected result is that the composition worked effectively in all ages from newborns to the geriatric, only the dosage amount needed to be adjusted accordingly.

14. Other than the invoice in Exhibit A and the papers reporting the results of the test, MD's Choice has not retained any additional documentation regarding the formulation of the enteral nutrition program provided to Lytle Creek Farms.

15. On or about October 12, 2001 MD's Choice performed a second test in which MD's Choice provided University of Tennessee, College of Veterinary Medicine (UTCVM) with a 4 part enteral nutrition program, of the similar composition as above, to treat a 6 year old, 100 kg, American Miniature Horse. UTCVM was provided with amounts of the 4 part program believed to be sufficient to treat the horse.

16. This testing was recorded on MD's Choice's invoice shown in Exhibit B. As with the invoice for Lytle Creek Farms, these invoice recorded the recipient of the program, the amount provided and instructions accompanying the program.

17. After providing the enteral nutrition program to the horse, UTCVM reported the results of the treatment to MD's Choice. The results of this treatment are discussed in paragraph [0115] of the Application.

18. The test result was unexpected because the 6 year old, 100 kg, American Miniature Horse had been failed to respond to aggressive medical therapy based on thorough diagnosis of its symptoms. In contrast, after providing the nutrition diet predetermined based on the mare's requirements for digestible energy, crude protein, calcium, and magnesium for maintenance and lactation, by the third day, the neurologic signs had disappeared and the serum triglyceride concentration had decreased to within normal range.

19. It is common knowledge that horses suffered from azotemia, hypocalcemia, metabolic acidosis, and elevated liver enzymes and total bilirubin are not normally recovered by themselves in three days without medical treatments.

Page 6
Serial No. 10/692,063
Affidavit

20. Other than the invoice in Exhibit B and the papers reporting the results of the test, MD's Choice has not retained any additional documentation regarding the formulation of the enteral nutrition program provided to UTCVM.

I hereby declare that *all statements* made herein of my own knowledge are true, and that all statements made on my information and belief are believed to be true; further that the statements were made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of my application or any patent issued thereon.

Oct 31, 2011
Date

By: Dr. David F. Davenport, DVM
Dr. David F. Davenport

EXHIBIT A

MDS CHOICE, INC
 2362 AIRBASE ROAD
 LOUISVILLE, TN 37777
 Telephone (865) 380-0950
 http://www.mdschoice.com

Invoice

DATE	INVOICE #
8/23/2001	2988

BILL TO LYTLE CREEK FARMS, INC. DR. JOHN BENNETT, DVM 6011 MANCHESTER PIKE MURFREESBORO, TN 37127 615-907-9888w 615-907-1323f	SHIP TO JIMMY OR JULIE
---	----------------------------------

P.O. NUMBER	TERMS	DUE DATE	REP	SHIP	VIA	OTB
	When Ordered	8/23/2001	MD	8/23/2001	UPS	

QUANTITY	ITEM CODE	DESCRIPTION	PRICE EACH	AMOUNT
20	PART 1 CRITICA...	LIQUID MEAL - ADD TO WARM H ₂ O (1 US GALLON... MAX T=100oC, LET INCUBATE @ ROOM TEMPERATURE AT LEAST 1 HOUR, DISCARD UNUSED PORTION AFTER 48 HOURS.	5.25	105.00
1	PART 2 COMPL...	LIQUID VITAMIN - MINERAL TRACE MIN - ANTIOXIDANT - 3oz PER DAY, REFRIGERATE AFTER OPENING	27.50	27.50
10	PART 3 GI SUPP...	GI SUPPORT - 1 SERVING PER DAY, DIVIDED BETWEEN MEALS - SMALL FOALS 1/3 TO 1/2 SERVING PER DAY.	5.84	58.40
40	PART 4 SUSPEN...	SUSPENDABLE FEED - MIX 2# W/ 5 GAL H ₂ O, RINSE WITH 5 GAL H ₂ O - AGITATE AT FEEDING	2.25	90.00
1	INSTRUCTIONS	INSTRUCTIONS - LIL & II CAN BE DOSE ADJUSTED FOR YOUNG FOALS. THE SUSPENDABLE FEED CAN BE USED W/ FOALS PREVIOUSLY ON SOLID FEED/HAY. TOTAL MAINTENANCE CALORIES & 2/3 OF REQUIRED PROTEIN FOR 1000# HORSE... CALL FOR CONSULTATION TO CUSTOMIZE TO SPECIFIC CASE.	0.00	0.00
			Subtotal	
			Sales Tax (0.0%)	
			Total	
			Payments/Credits	
			Balance Due	

Thank you for your order. We hope that you have a Great Day!!

Your order was cheerfully filled by: _____

Invoice

MDS CHOICE, INC

2362 AIRBASE ROAD
LOUISVILLE, TN 37777

Telephone (865) 380-0950

http://www.mdschoice.com

DATE	INVOICE #
8/23/2001	2988

BILL TO

LYTLE CREEK FARMS, INC.
DR. JOHN BENNETT, DVM
6011 MANCHESTER PIKE
MURFREESBORO, TN 37127
615-907-9888w 615-907-1323f

SHIP TO

JIMMY OR JULIE

PAID

P.O. NUMBER	TERMS	DUE DATE	REP	SHIP	VIA	OTB
	When Ordered	8/23/2001	MD	8/23/2001	UPS	
QUANTITY	ITEM CODE	DESCRIPTION	PRICE EACH	AMOUNT		
2	COMPLETE - AA FRSHP	COMPLETE FORMULA - LIQUID (AA) 10Z SERVING (SRP \$50) (PERSONAL SAMPLE) SHIPPING/HANDLING (1/2 HALF SRH OVER \$500 OF MEAL IN ORDER)	0.00 35.00	0.00 35.00		
			Subtotal	\$315.90		

Thank you for your order. We hope that you have a Great Day!

Your order was cheerfully filled by: _____

EXHIBIT B

MDS CHOICE, INC

2362 AIRBASE ROAD
LOUISVILLE, TN 37777
Telephone (865) 380-0950
<http://www.mdschoice.com>

Invoice

DATE	INVOICE #
10/12/2001	3200

BILL TO

UTCVM Large Animal Clinical Sciences
Attn: HAYDEN
2407 RIVER DRIVE
KNOXVILLE, TN 37996-4545

SHIP TO**PAID**

P.O. NUMBER	TERMS	DUE DATE	REP	SHIP	VIA	OTB
	Due on receipt	10/12/2001	DFD	10/12/2001	DAVE	

QUANTITY	ITEM CODE	DESCRIPTION	PRICE EACH	AMOUNT
35	PART 4 SUSPEN...	PART 4 SUSPENDABLE FEED - MIX 2# W/1.5 GAL H ₂ O, RINSE WITH .5 GAL H ₂ O - AGITATE AT FEEDING	0.00	0.00
20	PART 1 CRITICA...	PART 1 CRITICAL CARE MEAL - ADD TO WARM H ₂ O (1 US GALLON... MAX T=100°F LET INCUBATE @ ROOM TEMPERATURE AT LEAST 1 HOUR, DISCARD UNUSED PORTION AFTER 48 HOURS.	0.00	0.00
1	PART 2 COMEL...	PART 2 LIQUID VITAMIN - MINERAL TRACE MIN - ANTIOXIDANT - 3oz PER DAY, REFRIGERATE AFTER OPENING	0.00	0.00
10	PART 3 GI SUPP...	PART 3 GI SUPPORT - 1 SERVING PER DAY, DIVIDED BETWEEN MEALS - SMALL FOALS 1/3 TO 1/2 SERVING PER DAY.	0.00	0.00
			Subtotal	\$0.00
			Sales Tax (8.25%)	\$0.00
			Total	\$0.00
			Payments/Credits	\$0.00
			Balance Due	\$0.00

Thank you for your order. We hope that you have a Great Day!!

Your order was cheerfully filled by: _____